

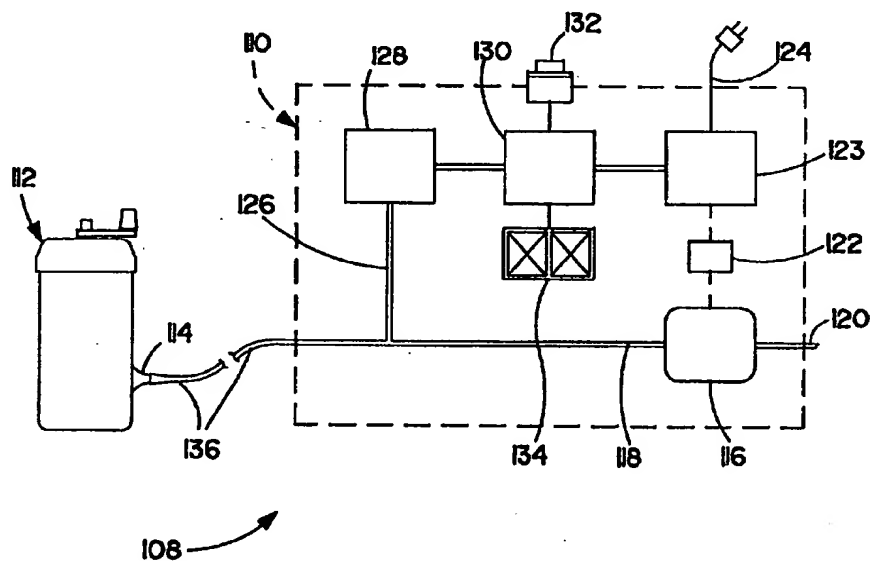


207

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : B01F 13/06	A1	(11) International Publication Number: WO 95/13862 (43) International Publication Date: 26 May 1995 (26.05.95)
<p>(21) International Application Number: PCT/US94/10903</p> <p>(22) International Filing Date: 8 November 1994 (08.11.94)</p> <p>(30) Priority Data: 08/153,220 16 November 1993 (16.11.93) US</p> <p>(71)(72) Applicant and Inventor: MURRAY, William, M. [US/US]; 2650 Spring Lane, Enola, PA 17025 (US).</p> <p>(74) Agents: HOOKER, Thomas et al.; Suite 304, 100 Chestnut Street, Harrisburg, PA 17101 (US).</p>		<p>(81) Designated States: AU, BB, BG, BR, CA, CZ, FI, HU, JP, KP, KR, LK, MG, MN, MW, NO, PL, RO, RU, SE, UA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>

(54) Title: MANUAL BONE CEMENT MIXING SYSTEM



(57) Abstract

A system (10) for mixing bone cement is disclosed. Dry PMMA powder and MMA liquid are mixed in a vacuum chamber (30) by a rotary mixer (40) having a pair of spaced mixing arms (74, 76). The rotary mixer (40) is manually rotated by a gear drive (36). The arms (74, 76) of the rotary mixer (40) follow continuous paths (80, 82), each path (80, 82) having a plurality of loops (84) at the wall (24) of the chamber (30) and curved portions (86) extending across the container between loops (84). The arms (74, 76) move through the cement, break bubbles and thoroughly mix the PMMA and MMA. Gas from broken bubbles is vacuum drawn from the mixer by a vacuum source (110) through a vacuum tube (106) which extends between the mixer and a vacuum source (110). The vacuum source (110) is automatically deactivated when the vacuum tube (106) is detached from the mixer.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

-1-

MANUAL BONE CEMENT MIXING SYSTEMField of the Invention

The invention relates to a system for mixing bone cement.

Description of the Prior Art

5 Bone cement is prepared by mixing a very fine cement powder, typically polymethylmethacrylate (PMMA), with a liquid monomer, typically methylmethacrylate (MMA). The cement is used as a grout for implanting prosthetic devices in live bone. Because the cement hardens quickly it is mixed in the operating room and is then
10 transferred directly to a prepared implantation site. The mixing of PMMA and MMA is performed in a housing under sterile conditions. During mixing, gas voids or bubbles are trapped in the viscous cement. These voids form hollow inclusions in the cured cement which weaken the cement and increase the possibility of cement
15 fracture and resultant loosening of an implanted prosthetic device.

Conventional in-bowl and in-syringe bone cement mixing devices have a vacuum mixing chamber, a lid which covers the chamber and seals the PMMA and MMA in the mixing chamber and a rotary mixer which extends through the lid and into the mixing chamber. The
20 mixer is manually rotated to mix the powder and liquid together and form bone cement. It is common practice to connect the mixing device to a vacuum source to reduce the internal pressure in the mixing device in an attempt to remove bubble gas from the cement during mixing.

25 Bone cement is mixed by placing fine PMMA powder and MMA liquid in a mixing chamber, either the bowl of an in-bowl mixer or the barrel of a syringe cartridge which is in turn placed in a housing. The mixing device is closed with a mixer extending into the cement powder and liquid and the device is connected to a
30 vacuum source. The mixer is manually operated for a measured time interval to mix the powder and liquid and form the bone cement.

When the mixing device is closed, the vacuum source very rapidly reduces the pressure within the closed mixing chamber and rapidly draws the relatively large volume of air between the very
35 fine dry particles of powdered PMMA out of the mixing chamber holding the PMMA. This occurs before the powder is fully wetted by the MMA and captured in a liquid or partially liquid body of cement.

The pressure within the chamber is often reduced sufficiently

-2-

rapidly to draw the air in the PMMA powder out of the powder explosively. Fine PMMA particles are entrained with the air and are drawn up from the bottom of the chamber, much like a geyser. The explosive extraction of air from between the particles of PMMA is undesirable because it may remove sufficient PMMA from the mixing chamber to change the composition of the bone cement and may coat the upper walls of the mixing device with powdered PMMA. PMMA powder may also be drawn into the vacuum line.

Rotation of the mixer in a conventional bone cement mixing device mixes the powdered PMMA and liquid MMA together to form a body of bone cement. During this mixing remaining air in the PMMA powder forms bubbles in the cement. Shallow bubbles located near the top of the cement tend to rise to the surface and break. Deep bubbles do not rise to the top of the viscous cement. As the mixer is moved through the cement it contacts bubbles in its swept path. These bubbles are broken by the mixer and withdrawn from the chamber. However, the mixer does not slice or break all of the bubbles in the cement. The path swept by a conventional mixer does not move the mixer through or sufficiently near all the bone cement in the mixing chamber to break all bubbles and release all bubble gas.

Bubbles deep in the liquid cement which are not sliced by the mixer are not removed from the cement. The viscosity of the cement prevents these bubbles from rising to the top of the cement and breaking. The bubbles in the fully mixed cement remain in the cement as the cement is removed from the mixing chamber and placed in an implantation site. The bubbles form hollow inclusions in the hardened cement. Joints formed by conventionally mixed bone cement are weakened by the inclusions.

Summary of the Invention

The invention is a system for uniformly mixing bone cement powder and liquid to make bone cement of the proper consistency having a reduced number of air bubbles. Powder geysers are eliminated. The arms of a rotary mixer are moved through a mixing chamber sufficiently close to each volume of cement in the chamber to thoroughly mix all of the cement to the proper consistency and break substantially all bubbles in the cement. Bubble gas is drawn from the mixing chamber by vacuum.

The mixing device is used with an automatic shutdown vacuum

-3-

source including a vacuum pump and an automatic shutdown control for preventing drawing contaminants into a vacuum tube after the tube is removed from the mixer.

Bone cement is mixed by placing the proper amounts of PMMA and MMA in the mixing chamber, placing a cap on the chamber with a rotary mixer extending into the chamber and connecting the chamber to the automatic shut-down vacuum source through a vacuum tube. The vacuum source withdraws air from the mixing chamber without drawing powdered geysers during withdrawal of air trapped between particles of dry PMMA. During mixing the vacuum source reduces the pressure within the chamber to withdraw bubble gas from the cement and thereby prevent hollow inclusions in the cement, when hardened. Mixing is done in a sterile field.

After the cement has been properly mixed, the vacuum tube is removed from the mixing device, the cap and mixer are removed and the mixed cement is promptly applied to the application site and the stem of a prosthetic element is embedded into the cement. The cement hardens to form a joint securing the stem to the surrounding live bone.

It is important to flow the liquid mixed bone cement to the application site as promptly as possible in order to assure that the cement is sufficiently viscous to flow into the implantation site and receive and surround the stem of the prosthetic element. The automatic shutdown vacuum source facilitates very prompt flowing of the mixed bone cement to the application site by permitting the surgeon or operating room attendant to remove the vacuum tube from the mixing device, drop the tube and then directly proceed to opening the chamber and flowing the cement to the implantation site without the necessity of pausing to locate and then deactivate a vacuum control switch. The vacuum source senses the sudden increase in pressure when the vacuum tube is removed from the mixing device and automatically shuts down the vacuum pump. This automatic shutdown also provides added safety of operation by avoiding the possibility of inadvertently flowing operating contaminants into the mixing chamber when the chamber is opened.

Other objects and features of the invention will become apparent as the description proceeds, especially when taken in conjunction with the accompanying drawings illustrating the invention, of

--4--

which there are nine sheets and two embodiments.

Description of the Drawings

Figure 1 is a vertical sectional view taken through a first embodiment bone cement mixing device;

5 Figure 2 is a sectional view taken along line 2--2 of Figure 1;

Figure 3 is an enlarged exploded view illustrating the components of the drive of the mixer shown in Figure 1;

10 Figure 4 is a sectional view taken along line 4--4 of Figure 1 illustrating the mixing paths swept by the mixer;

Figure 5 is a view of an alternative embodiment vacuum port for the mixer;

Figure 6 is a vertical sectional view taken through a second embodiment bone cement mixing device;

15 Figure 7 is a sectional view taken along line 7--7 of Figure 6;

Figure 8 is an enlarged exploded view illustrating the components of the drive of the mixer shown in Figure 6;

20 Figure 9 illustrates a bone cement mixer and an automatic shutdown vacuum source;

Figure 10 is a sectional view illustrating the lower end of a second embodiment cement mixer in the mixing device of Figure 1; and

25 Figure 11 is an isometric view of the piston and lower end of the mixer of Figure 10.

Description of the Preferred Embodiments

30 First embodiment mixing device 10 shown in Figures 1-4 is used to mix bone cement powder and a liquid under vacuum to make a body of uniformly mixed bone cement having reduced bubbles. The bone cement powder is typically polymethylmethacrylate (PMMA) and the liquid mixed with the powder is typically a liquid monomer methylmethacrylate (MMA). Powder geysers are eliminated.

Mixing device 10 includes a hollow housing 12 having an open top, a cylindrical sidewall and a closed bottom wall with an integral cartridge socket 14 projecting up from the bottom wall. The housing also includes integral vacuum tube attachment fitting 16 or chamber port located on the sidewall near the closed bottom. The fitting defines a passage extending through the housing sidewall. A restriction 18 in the fitting limits the outward flow of air

--5--

through the fitting. As shown in Figure 1, one end of flexible vacuum tube 20 is connected to fitting 16. The other end of the tube is attached to a conventional vacuum source or to specialized vacuum source 110 shown in Figure 9. The restriction 18 prevents
5 a very sudden reduction of pressure within the housing when the housing is first connected to a vacuum source without limiting pressure reduction within the housing. The pressure in the housing is reduced sufficiently slowly to prevent powder PMMA geysers. During mixing, the pressure in the device is reduced to the
10 pressure of the source to withdraw released bubble gas.

It should be noted that the rate of outflow of air from the interior of the housing may be suitably reduced by placing an airflow restriction, like restriction 18, anywhere in the path of flow and through the vacuum source. With most types of vacuum
15 pumps, the restriction may even be placed on the pump's outflow side. A number of restrictions, located at different points along the path of air flow, may be used to provide the total amount of restriction which is required. Plural restrictions can facilitate reduction of initial flow of air from the mixing device to
20 compensate for the properties of the particular operating room vacuum system, including the length and interior diameter of the vacuum tube, the vacuum achievable by the vacuum pump and the rate at which the pump exhausts air from the mixing device.

A hollow cylindrical syringe cartridge 22 having opposed open
25 and closed ends, a cylindrical sidewall 24 and a diameter smaller than the diameter of housing 12 is fitted within the housing with the lower end of the cartridge seated in socket 14. Piston 26 closes the lower end of the cartridge. The piston has a flat upwardly facing mixing face 28. The sidewall 24 and the mixing
30 face 28 define cement mixing chamber 30. Filling funnel 32 is removably mounted on the upper open end of cartridge 22 to facilitate pouring PMMA powder and liquid MMA into the mixing chamber. The funnel is removed after mixing has been completed and before the cartridge is loaded in an applicator gun for flowing the
35 mixed bone cement to an application site.

Cap 34 is fitted on the open upper end of housing 12 and serves to close the interior of the housing. The cap supports a manually operated three gear mixer drive 36. Crank arm 38 on the top of the cap actuates the drive to rotate mixer 40 about mixer

-6-

axis 42 and simultaneously move the mixer in a circle around central chamber axis 44. The housing and cap may be made from plastic or other suitable material.

Three gear drive 36 includes an input drive shaft 46 located
5 on chamber axis 44 and extending through the thickness of cap 34 with ends above and below the cap. Crank arm 38 is attached to the upper end of shaft 46 and carries a knob 48 extending upwardly from the outer end of the crank arm to permit manual rotation of the shaft. The drive 36 also includes an input gear 50 and hub 52
10 located on the lower end of shaft 46 inside the cap. An interior gear 54 is formed on the circumference of recess 56 in cap 34 and surrounds and is concentric with the chamber axis 44 and input gear 50 which is also located in the recess. Mixer gear 58 is located in the recess between the input gear and the interior gear and
15 includes teeth engaging the teeth of the input gear and the teeth of the interior gear. The mixer gear 58 is mounted on a short rotary output shaft 60 which extends into the bore of a mounting bushing 62 on circular plate 64. The output shaft extends about halfway through the bore. The plate covers the recess 56 and is
20 held against lower surface of cap 34 by a retainer collar 66 which has an inwardly facing lip 68 extending under the circumferential edge of plate 64. The collar permits rotation of the plate around the chamber axis 44 as the gear 50 is rotated by crank arm 38. The plate rotates on the lip. Hub 52 on gear 50 extends through a
25 central opening in plate 64 to permit relative rotation of the plate and gear.

Rotary mixer 40 is removably attached to shaft 60. The mixer includes a short central shaft 70 having an upper end 72. End 72 is extended into the bore of bushing 62 and is removably attached
30 to the lower end of output shaft 60 so that rotation and movement of mixer gear 58 rotates and moves the mixer. The connection between shafts 60 and 70 is of conventional design and permits ready attachment and removal of mixers so that device 10 may be used to mix a number of batches of cement.

35 The mixer 40 includes a pair of vertical mixing arms 74 and 76 each extending parallel to central shaft 70 along the length of the mixing chamber 30 in cartridge 22 and spaced an equal distance to either side of the shaft. The upper ends of arms 74 and 76 are joined to the central shaft at the top of the chamber. The lower

-7-

ends of the arms are joined by cross arm 78. The arm 78 is located immediately above the mixing surface 28 of piston 26. The corner between the lower ends of vertical arms 74, 76 and the cross arm closely conforms to the radius at the lip of the piston 26.

5 Arms 74 and 76 are equally spaced on opposite sides of central shaft 70 and are spaced apart from each other a distance slightly less than the radius of the interior of the mixing chamber 30. Each arm is spaced from mixer axis 42 a distance approximately equal to one quarter of the diameter of the mixing chamber. In
10 this way, as shown in Figures 1 and 4, rotation of the mixer about axis 42 and movement or translation of the mixer axis 42 around axis 44 moves each vertical arm 74, 76 through a continuous path 80, 82. In Figure 4, path 80 is shown stippled in order to distinguish the path visually from path 82. In each path the arms
15 are swept through a number of loops 84 spaced around the circumference of the chamber sidewall 24 very close to the sidewall, and are moved along smooth curved sections 86 extending between successive loops 84 and passing through the chamber axis 44

Operation of the mixing device 10 will now be described.

20 Syringe cartridge 22 is placed in the empty housing 12 with the piston end of the cartridge seated in socket 14. A filling funnel 32 is placed on the open end of the syringe cartridge as shown. The required amounts of dry PMMA powder and MMA liquid are poured into mixing chamber 30. The combined volume of the PMMA and
25 MMA may fill the chamber to level 88, although greater or smaller volumes of bone cement may be mixed as required. See Figure 1.

After the PMMA and MMA are placed in the chamber, the cap 34 with attached rotary mixer 40 is placed on the open end of the housing with mixer 40 extended down into the mixing chamber and the
30 PMMA and MMA mixture and cross arm 78 immediately above mixing surface 28 as shown in Figure 1. The cap seals the PMMA, MMA and trapped air in housing 12. With the vacuum source operating, vacuum tube 20 is connected to fitting 16 to connect the interior of the mixer to the vacuum source. Mixing is started by turning
35 crank 38.

When vacuum tube 20 is attached to fitting 16 restriction 18 prevents very rapid reduction of the pressure in the interior of the housing during initial mixing and wetting of the PMMA powder in chamber 30. In this way, the pressure within the chamber is slowly

reduced to the pressure of the vacuum source for efficient removal of air from between particles of dry PMMA without forming explosions or geysers of PMMA powder. Air trapped in the mixture, including bubble gas, is vacuum withdrawn without entraining dry cement particles. After initial mixing of the cement, the pressure in the chamber is lowered to the pressure of the vacuum source.

The PMMA and MMA are mixed for a period of about 90 to 120 seconds. During the mixing cycle, crank 38 is rotated in one direction to rotate shaft 46 and gear 50 in the same direction. Rotation of the crank and input gear 50 rolls the mixer gear 58 around the interior gear 54 in a direction of rotation about axis 42 opposite to the direction of rotation of the crank around axis 44. The mixer is moved in a circle around axis 44 at a slower speed than the crank because there are a greater number of teeth on the interior gear than on the input gear.

During mixing, the mixer moves or translates in a circle around chamber axis 44, the mixer rotates about axis 42 and the vertical mixer arms 74 and 76 follow the continuous paths 80 and 82 shown in Figure 4. By using the gear ratios shown, each continuous path includes ten like loops 84 which are spaced around the circumference of chamber 30 and joined by smooth curved sections 86 passing through chamber axis 44. During each 360 degree rotation of mixer 40 about mixer axis 42 each mixing arm 74 and 76 is moved from the end of one loop along a curved section 84 to the next loop. The individual adjacent loops swept by the two mixer arms are offset by 18 degrees. See Figure 4. The rotary mixer is rotated three times around axis 44 in order to move the mixing arms along the complete lengths of paths 80 and 82.

Rotation of the crank during mixing moves the arms throughout the chamber sufficiently close to all of the cement in the chamber to thoroughly mix the bone cement components and slice through substantially all of the gas bubbles trapped in the cement. The liquid cement flows in the chamber during mixing to further assure the cement is thoroughly mixed and bubbles are sliced. Released bubble gas is drawn away by vacuum. Mixing is enhanced by sweeping arms 74 and 76 close past the sidewall of chamber 30 as they move through loops 84. As the arms move past the sidewall, cement and liquid adhered to the arms and to the sidewall are mixed with the body of cement in chamber 30. Cement and liquid adhered to the

- 9 -

mixing face 28 and cross arm are likewise mixed with the cement in the chamber.

As the mixing arms are moved around paths 80 and 82, the arms slice through bubbles in the mixture and break bubbles. It is believed that the arms displace the viscous mixture to either side of the arms and create voids or spaces directly behind the arms with each void extending vertically to and through the surface of the cement body at level 88. The arms extend from the bottom of the chamber up to and past the top of the body of cement in the chamber. Gas from bubbles broken by the arms is believed to flow up the voids and is vacuum-drawn from the mixing device. Shallow bubbles tend to rise through the cement to the surface 88 and break. During mixing, the cement flows in the chamber so that substantially all deep bubbles are broken by the arms and the freed bubble gas is vacuum withdrawn.

At the completion of the mixing cycle, the vacuum in the chamber is released by removing tube 20 from fitting 16, the cap is removed from the housing and the rotary mixer is withdrawn from the mixing chamber. The syringe cartridge containing the body of freshly mixed bone cement is removed from the housing socket, the funnel is removed and the cartridge is placed in a bone cement applicator. The well mixed and essentially bubble-free bone cement is then flowed to a prepared implant site and the mounting stem of a prosthetic device is extended into the cement. The cement rapidly hardens to form a strong joint securing the prosthetic element in place. The joint is substantially free of gas inclusions.

As indicated, the mixer 40 is removably connected to shaft 60. After mixing and opening of the housing, the mixer 40 is detached from shaft 60 and discarded. A new mixer may be inserted into bushing 62 to engage shaft 60 and prepare device 10 for mixing another batch of bone cement.

Figure 5 illustrates a second embodiment vacuum tube attachment fitting 100 formed in the wall of a housing 102 like housing 12 of mixing device 10. The fitting 100 is similar to fitting 16 but has a concave exterior shape and a small diameter tube mounting end 104 facing outwardly from the housing. One end of small diameter vacuum tube 106 is fitted on end 104. The other end of the tube is attached to a vacuum source. This tube may be

-10-

of a diameter approximately equal to the diameter of tubing which is used conventionally for flowing intravenous fluids and is appreciably smaller in diameter than the diameter of conventional vacuum tubing 20. The diameter of conventional vacuum tubing is approximately 0.375 inch while the interior diameter of the small vacuum tube is less than 0.1 inch. The interior diameter selected may be made sufficiently small to form a restriction which reduces the outward flow of air from the interior of the housing during initial mixing to a rate insufficient to lift or draw dry PMMA powder up from the mixing chamber 30. Air flowed through tube 106 reduces the pressure in the housing to aid in removal of bubble gas.

Different types of vacuum sources may be used to withdraw air from device 10 during bone cement mixing. These vacuum sources include the operating room vacuum system, a manually actuated dedicated pump operated by compressed gas or electricity, or an automatic shutdown vacuum source shown in Figure 9.

Figures 10 and 11 illustrate a second embodiment mixer 90 similar to mixer 40 in mixing device 10. Mixer 90 includes a central shaft like shaft 70 and a pair of spaced parallel mixing arms 91 and 92 like arms 74 and 76. Cross arm 93 joins the lower ends of the mixing arms 91 and 92. The mixer 90 is removably attached to shaft 60 like mixer 40.

The cross arm 93 includes a pair of angled mixing blades 94 joined at the center of the arm. Each blade extends from the center of the cross arm to the lower end of one of the mixing arms 91, 92. As shown in Figure 11, each blade includes a lead edge 95 located immediately above the mixing face 28 of piston 26 and a deflector 96 sloping upwardly and rearwardly of the lead edge. The lead edges 95 of the two blades 94 face in opposite directions.

During bone cement mixing, mixer 90 is rotated in a direction to rotate the leading edges around the mixing face 28 so that the powdered cement, liquid and cement mixture on the face of the piston is scraped from the face and deflected upwardly into the main body of cement in the mixing chamber and is thoroughly mixed with the body of cement. The mixture in the main body of cement in the chamber is also drawn down into the spaces behind the blades during rotation of the mixer to further enhance mixing. In this way, mixer 90 positively scrapes the cement constituents from the

-11-

top of the piston and mixes them with the body of liquid cement in the mixing chamber. During mixing arms 91 and 92 follow paths like paths 80 and 82 to thoroughly mix the cement and break bubbles. Released bubble gas is withdrawn as previously described.

5 Suitable indicia such as an arrow may be affixed to the top of cap 34 or on the handle to indicate the proper direction of rotation of handle 38 required to rotate mixer 90 so that the lead edges of the mixing blades are moved forward around the top of the piston and scrape material from the piston. Mixers 40 and 90 may
10 be made from metal or molded plastic.

A second embodiment mixing device 210 is shown in Figures 6-8. The second embodiment mixing device is similar to the first embodiment mixing device 10 but uses a manually operated two gear mixer drive 212.

15 Cap 34 supports drive 212. Crank arm 38 actuates the drive to simultaneously rotate and move the mixer 40 in the same manner and around the same paths 80 and 82 as previously described. Drive 212 includes input drive shaft 46 located on chamber axis 44 and extending through cap 34 and circular plate 214. Crank 38 is
20 attached to the upper end of the shaft. Circular plate 214 is similar to circular plate 64 except that hub 216 surrounds and is connected to shaft 46. The shaft holds the plate against the interior surface of the cap. The plate covers recess 56 in cap 34. Hub 216 of plate 214 is located within recess 56 with the top of
25 the hub in contact with the upper surface of the recess. See Figure 6.

Drive 212 also includes mixer gear 58 and interior gear 54 which is formed on the circumference of recess 56. The teeth of mixer gear 56 are engaged with the teeth of the interior gear. The
30 mixer gear is mounted on short rotary output shaft 60 which extends into hub 62 and is removably connected to shaft 70 to rotate mixer 40.

The housing 18 of mixing device 210 may include either a first embodiment vacuum hose attachment fitting 16 shown in Figure 6 or
35 a second embodiment vacuum hose attachment fitting 100 shown in Figure 5.

Operation of mixing device 210 will now be described.

After the required amounts of PMMA and MMA are placed in chamber 30, the cap 34 supporting drive 212 and mixer 40 is placed

-12-

on the top of housing 18 sealing the contents of the housing with the mixer extending into the PMMA and MMA mixture. Vacuum tube 20 is then connected to fitting 16.

The PMMA and MMA are mixed by rotating crank 38 clockwise. As
5 the crank is rotated clockwise, shaft 46 and plate 214 also rotate clockwise. The mixer gear 58 is moved clockwise around axis 44 and this gear is rotated about axis 42 in a counterclockwise direction. Arms 74 and 76 follow the continuous paths 80 and 82 shown in Figure 4 and gas is withdrawn from the mixture in the manner
10 previously described. After mixing is completed, the tube is disconnected from the fitting. The cap is opened and the cement is flowed to an application site as described.

Figure 9 illustrates a system 108 for mixing bone cement. The system includes an automatic shutdown vacuum source 110, a bone
15 cement mixing device 112 and a vacuum tube 136 joining the source and device. Device 112 may be identical to either device 10 or device 210 and includes a vacuum tube attachment fitting 114 like either fitting 16 or 100.

The automatic shutdown vacuum source 110 includes a vacuum
20 pump 116, a low pressure inlet line 118 connected to the pump inlet port and a high pressure discharge port 120. The pump 116 is powered by electric motor 122 which is connected to a source of electricity through power line 124. The vacuum line 126 connects the inlet line 118 to an electronic pressure transducer 128 which
25 in turn is electrically connected to shutdown control circuit 130. A manually activated start switch is connected to circuit 130. Power switch 123 in line 124 is controlled by circuit 130. The control circuit 130 is of conventional design. The electronic pressure transducer 128 may be of the type manufactured by
30 Motorola, Inc. of Schaumburg, Illinois.

Power switch 123 is normally open. Actuation of momentary-type start-up switch 132 closes the switch 123. The control circuit 130 opens the switch 123 to turn motor 122 off when a sudden increase in pressure in line 126 is sensed by transducer
35 128. A vacuum indicator 134, controlled by circuit 130, provides a visual indication of the level of vacuum in the interior of device 112 during cement mixing. The indicator 134 may have an analog or digital read out.

Bone cement is mixed in the operating room. Mixer 112 is

13-

maintained in a sterile field during mixing. Cement is mixed using vacuum source 110 by placing a syringe cartridge in an empty housing, and attaching one end of sterile vacuum tube 136 to fitting 114. The other end of the tube is connected to the inlet line 118. At this time, the pump is not in operation. The PMMA and MMA to be mixed are placed in the mixing chamber. The cap is then attached to the top of the housing with the mixer extending into the mixing chamber. An assistant actuates switch 132 to supply power to control circuit 130, close switch 123 and actuate motor 122 and the vacuum pump 116. The vacuum pump withdraws air from the mixer without forming powder geysers. The cement is mixed and bubble gas is removed, as previously described. During mixing, the attendant monitors indicator 134 to assure that the pressure within the mixer has been properly reduced for efficient removal of bubble gas.

After mixing has been completed, vacuum tube 136 is disconnected from fitting 114 and falls away, thereby allowing the pressure within the mixing device to rise to atmospheric pressure. The device is maintained in the sterile field at the time the vacuum tube 136 is removed from fitting 114 so that sterile air flows into the interior of the device and does not contaminate the freshly mixed cement. The end of the tube may fall into a non-sterile field. The cap is then removed from the housing, the cartridge withdrawn, the mixed cement is flowed to the application site, and the prosthetic device is embedded in the cement. These operations are time-critical in order to introduce the cement to the application site at a time when its viscosity is as low as possible.

Vacuum source 110 automatically shuts down the vacuum pump 116 without manual intervention when vacuum tube 136 is removed from fitting 114. The electronic pressure transducer 128 senses the sudden increase of pressure in line 118 resulting from removal of the tube from the fitting and the control circuit then immediately opens switch 123 to deactivate pump 116. Shutdown occurs automatically without a surgeon or attendant having to take the time to search for and actuate a shutdown switch or pedal to deactivate the vacuum pump.

Automatic shutdown of the vacuum source eliminates a variable interval delay in the time critical process of mixing and

-14-

dispensing bone cement. Cement is delivered to the application site without wasting time to locating and actuating a shutdown switch.

Furthermore, use of the automatic shutdown control eliminates the possibility of people in the operating room shutting down the vacuum pump while the vacuum line is connected to the mixing device. Such premature shutdown of the vacuum pump could result in contamination of the bone cement in the mixing device due to vacuum aspiration of non-sterile material from the non-sterile pump area into the mixing chamber through the vacuum line.

While I have illustrated and described a preferred embodiment of my invention, it is understood that this is capable of modification, and I therefore do not wish to be limited to the precise details set forth, but desire to avail myself of such changes and alterations as fall within the purview of the following claims.

WHAT I CLAIM AS MY INVENTION IS:

1. A system for mixing bone cement comprising,
 - a) a device for mixing bone cement having a hollow mixing chamber, a mixer extending into the chamber, a mixer drive
5 for rotating the mixer in the chamber, and a chamber port;
 - b) said vacuum tube having one end attached to said chamber port and a second end; and
 - c) a vacuum source including a vacuum pump having an inlet port connected to the second end of the vacuum tube, and
10 vacuum pump shutdown means for automatically deactivating the pump when the pressure at the inlet port suddenly rises.
2. The device of claim 1 including an electric motor for the pump, a power line for the motor and wherein the vacuum pump shutdown means includes an electronic pressure transducer connected
15 to the inlet port, a power switch connected in the power line for the motor and circuit means for opening the switch when the transducer senses a sudden rise in the pressure at the inlet port.
3. A system as in claim 2 including indicator means for indicating the pressure at the inlet port.
- 20 4. A system for mixing bone cement including a closed bone cement mixing chamber, a mixer in the chamber for mixing bone cement powder and bone cement liquid together to form a body of viscous bone cement, a vacuum source, a tube connection joining the vacuum source to the interior of the mixing chamber so that the
25 source reduces the pressure within the chamber and withdraws gas from the chamber, and vacuum source shutdown means for sensing an increase in pressure when the vacuum source is disconnected from the mixing chamber and then automatically deactivating the vacuum source in response to the sensed pressure increase.
- 30 5. A system as in claim 4 wherein the shutdown means includes an electronic pressure transducer.
6. A system as in claim 5 including a start switch for powering the vacuum source and the shutdown means.

1/9

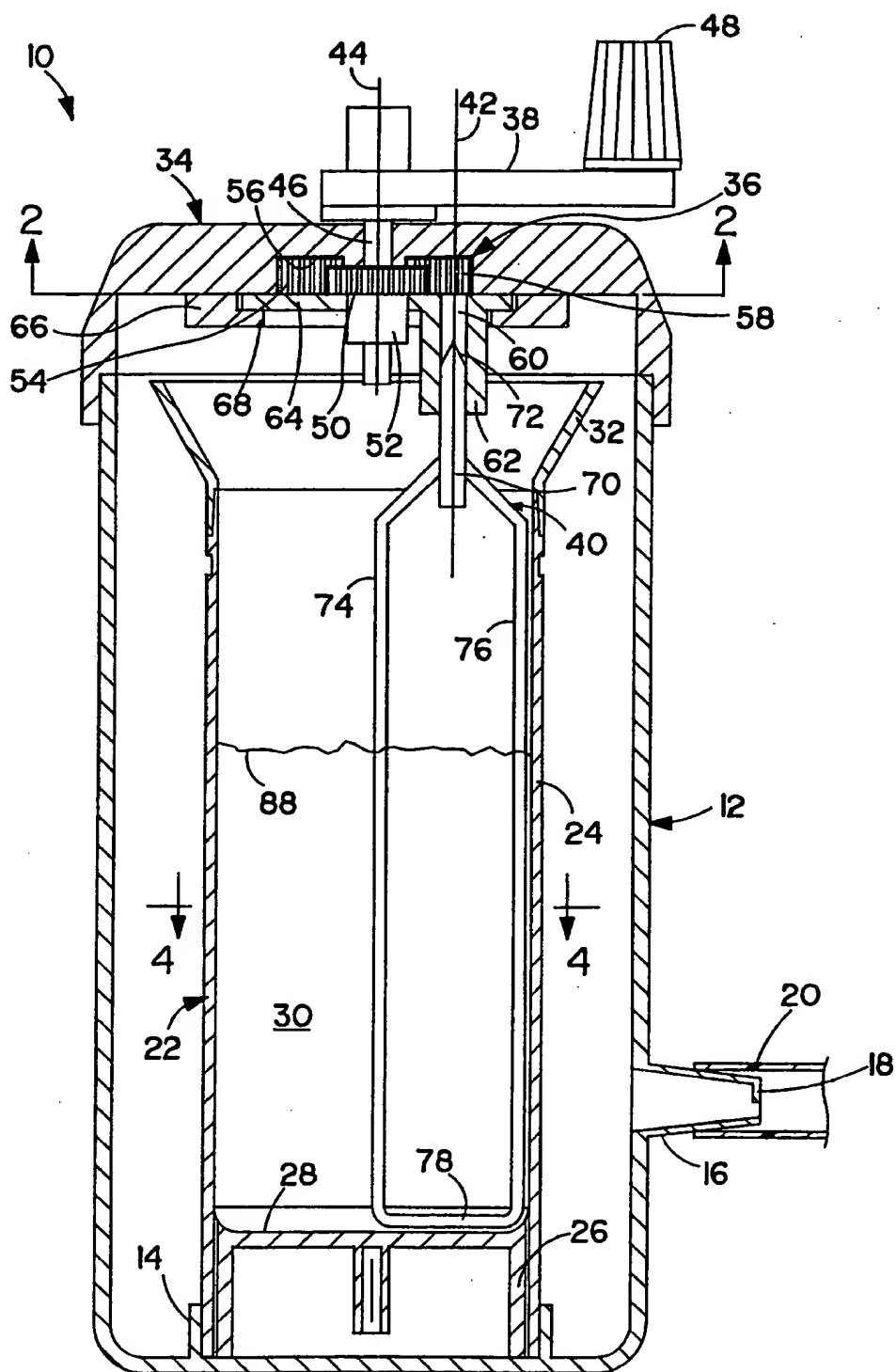


FIG. 1

2/9

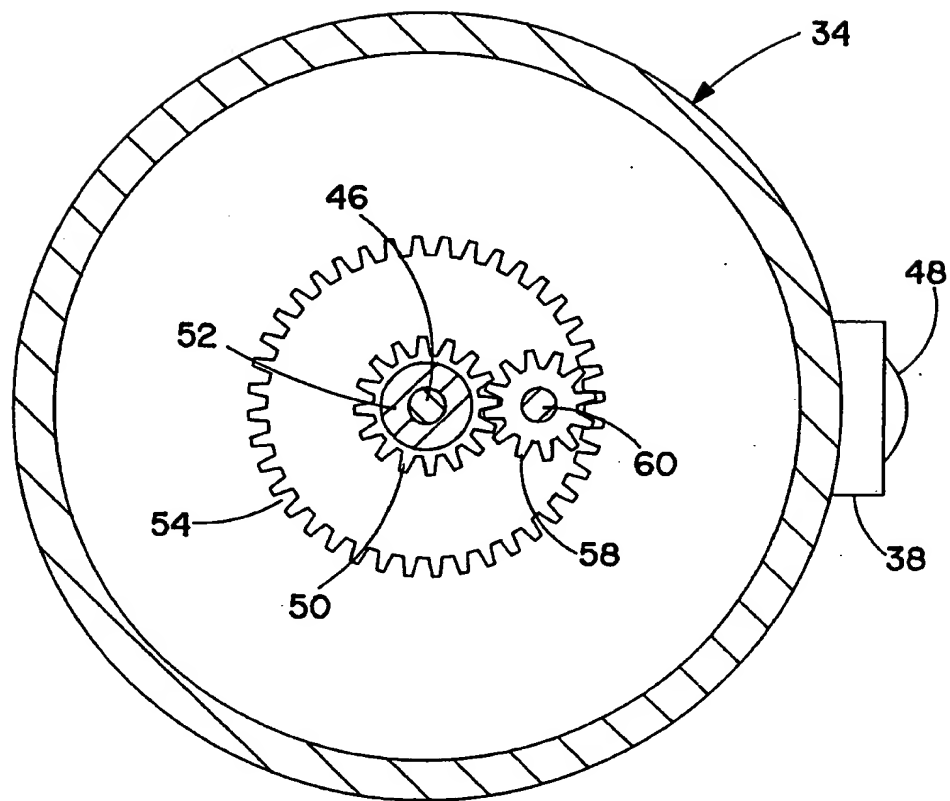


FIG. 2

3/9

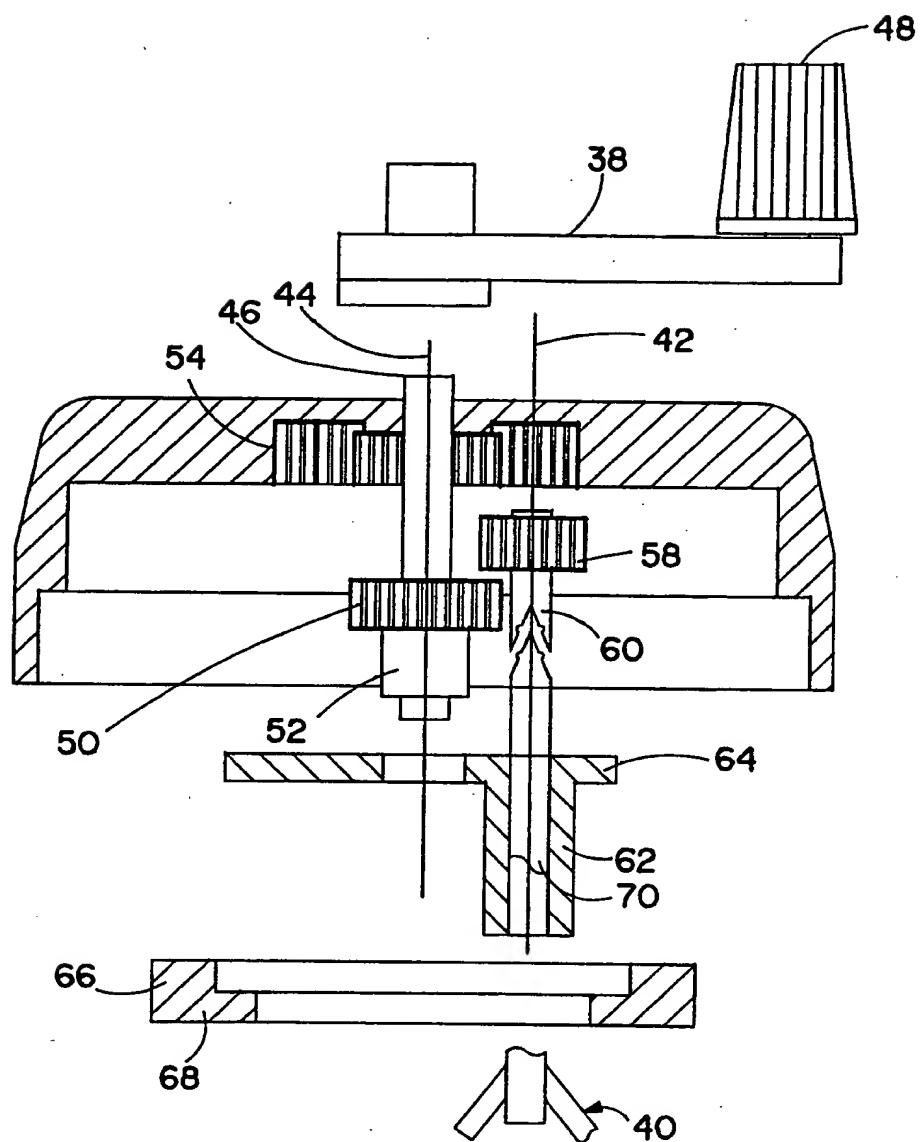


FIG. 3

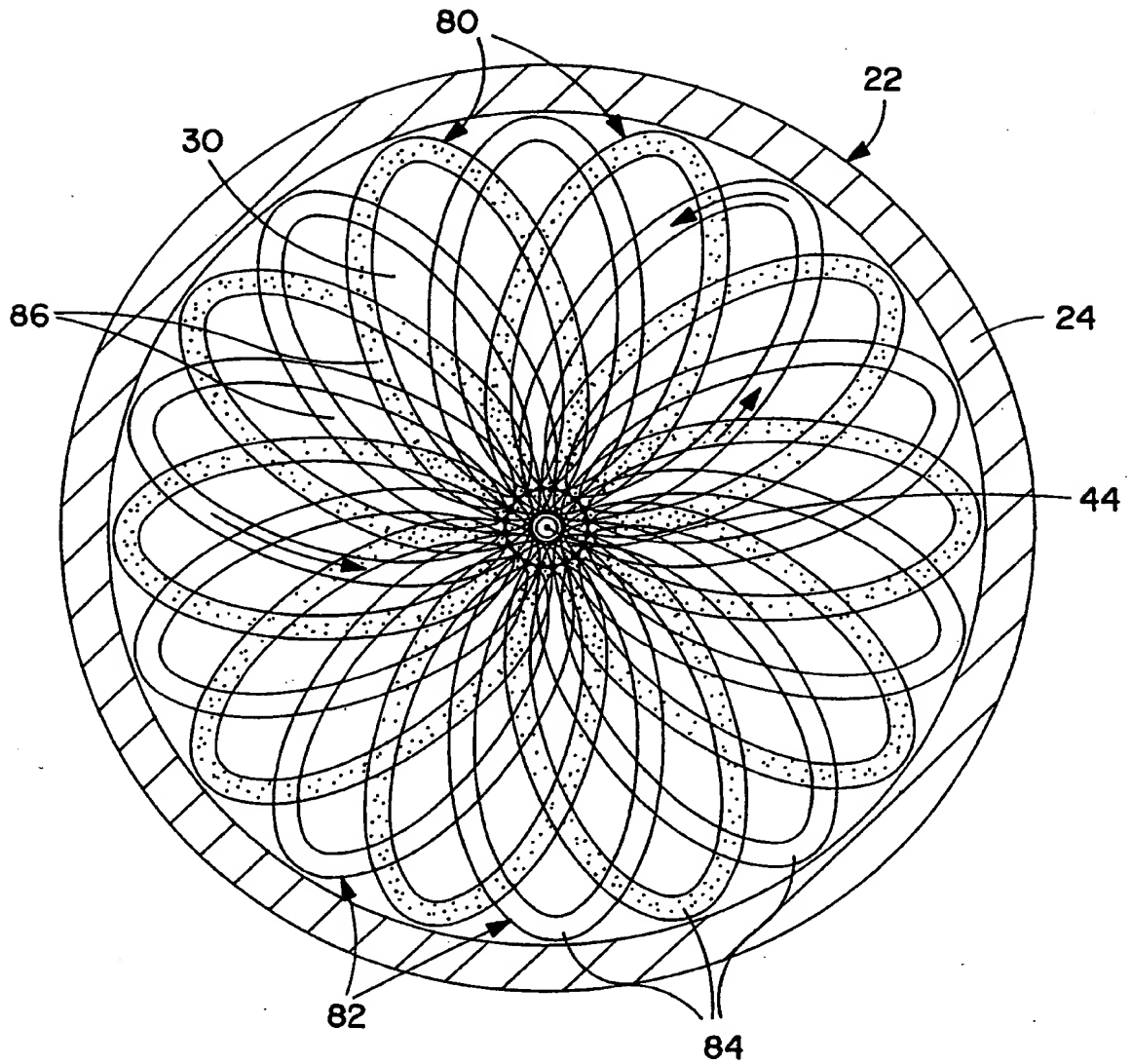


FIG. 4

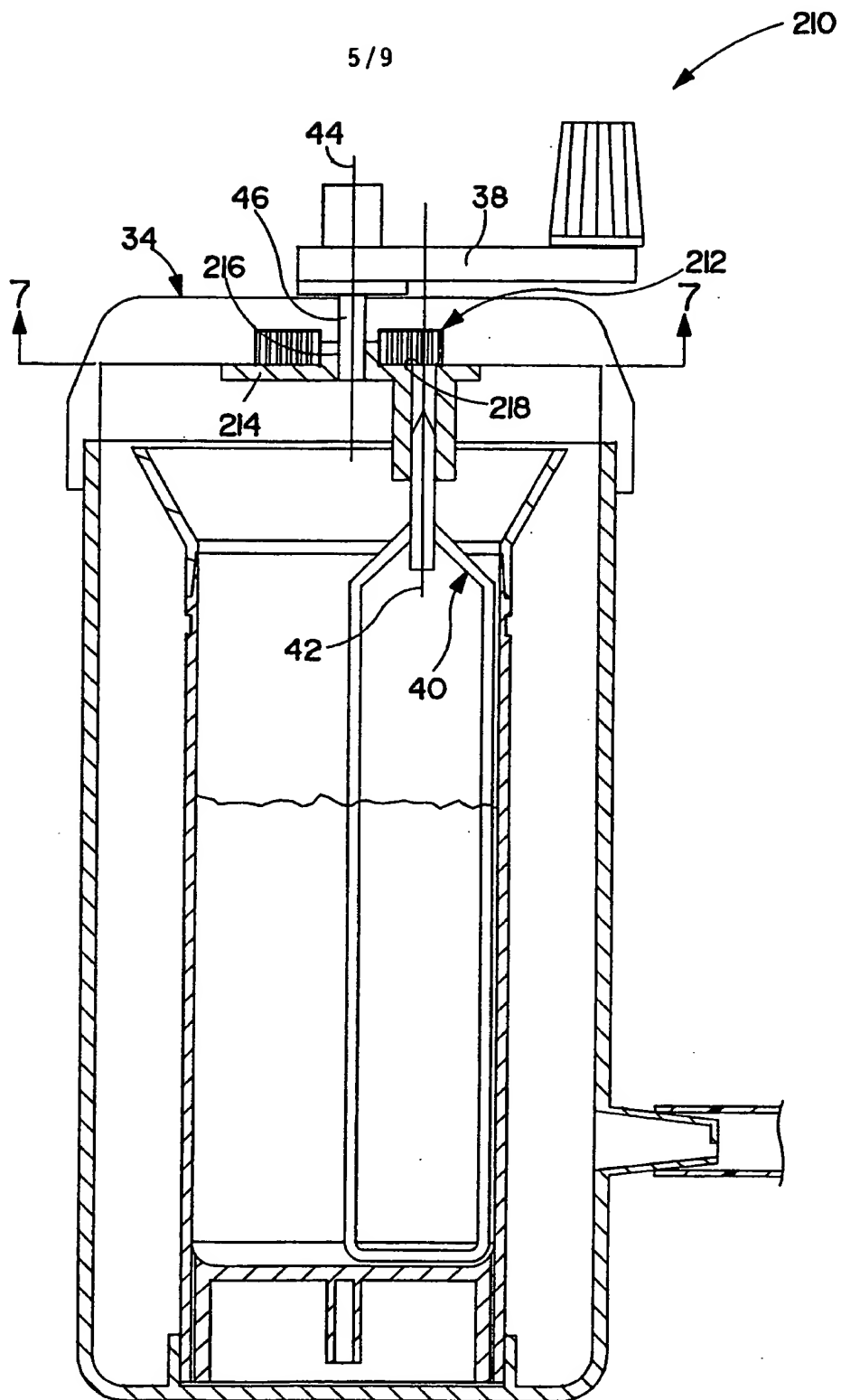


FIG. 6

6/9

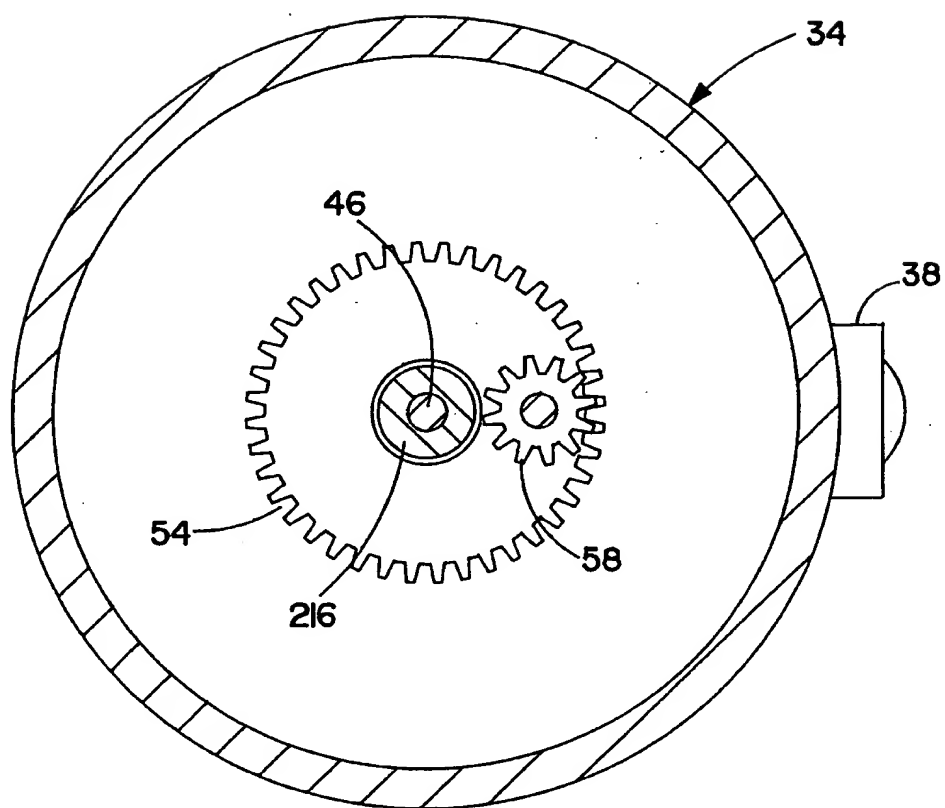


FIG. 7

7/9

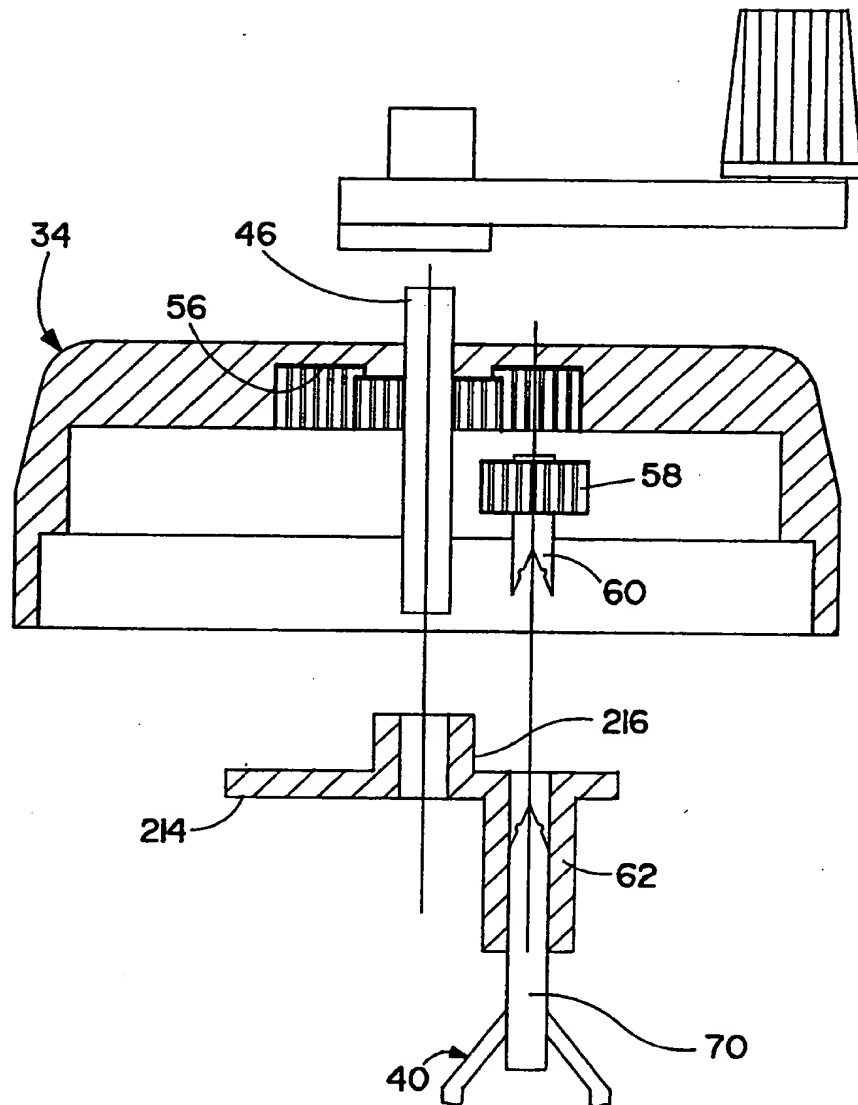


FIG. 8

8/9

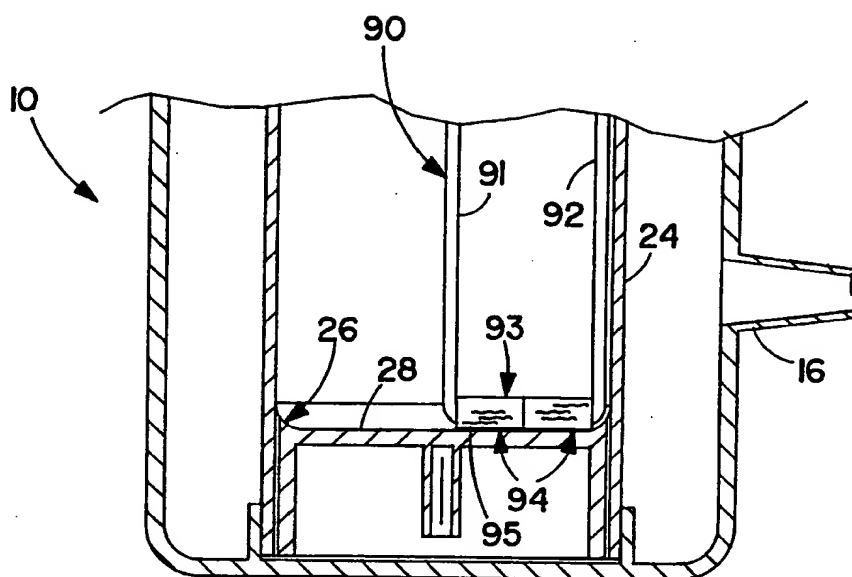


FIG. 10

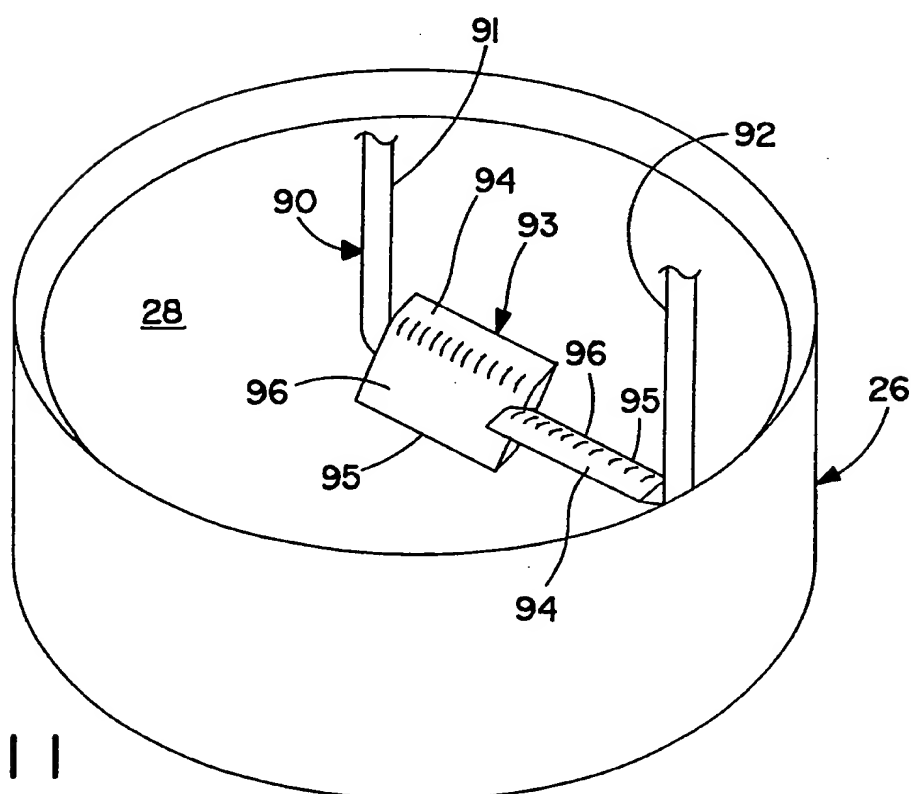


FIG. 11

9/9

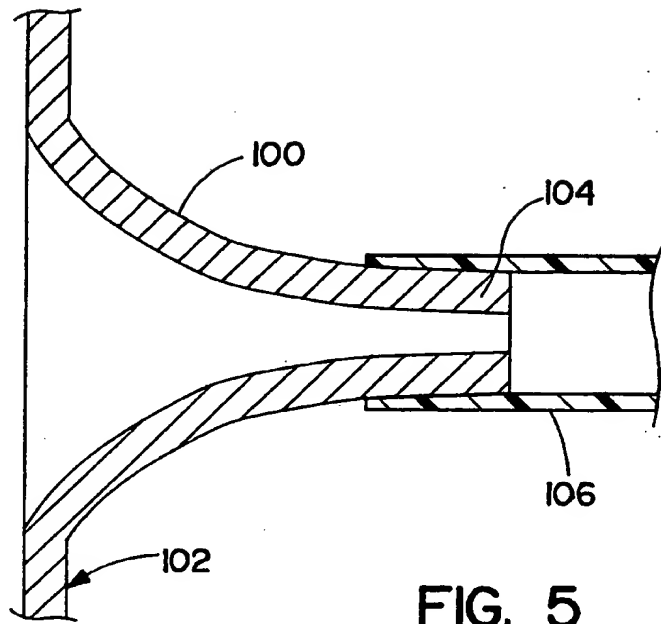


FIG. 5

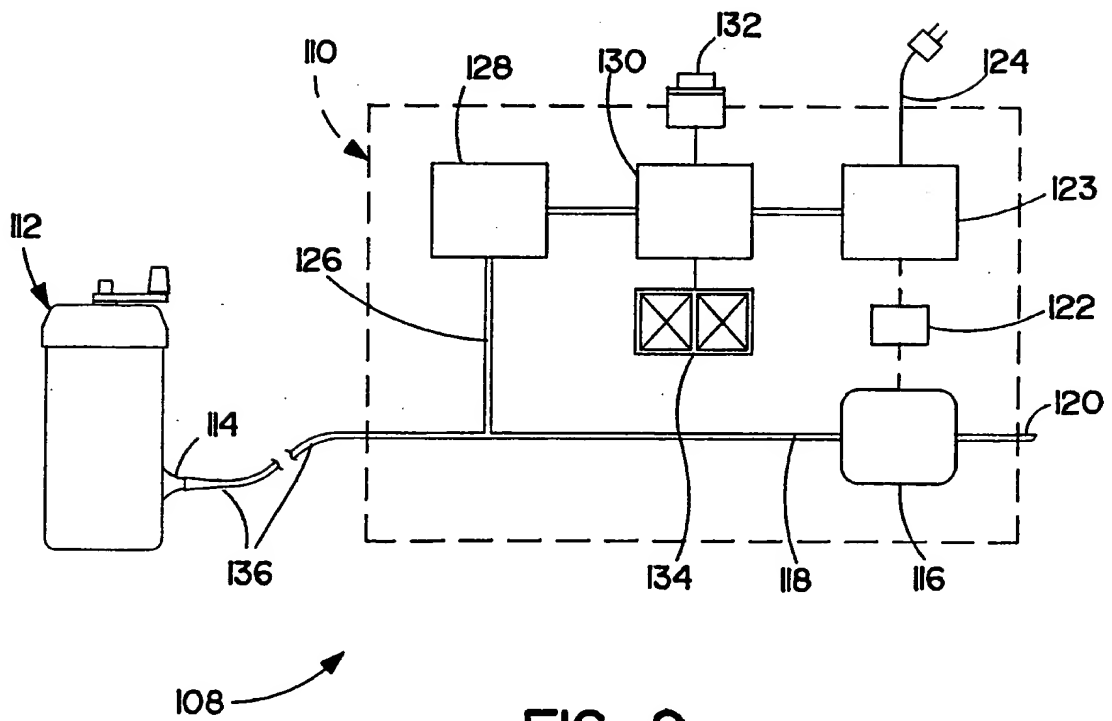


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/10903

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B01F 13/06

US CL :366/139, 142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 366/139, 142; 494/61

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,185,072 (PUDEBAUGH ET AL) 22 January 1980, see entire document.	NONE
A	US, A, 4,721,390 (LIDGREN) 26 January 1988, see entire document.	NONE
A	US, A, 4,758,096 (GUNNARSSON) 19 July 1988, see entire document.	NONE

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

09 DECEMBER 1994

Date of mailing of the international search report

05 JAN 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

RANDALL E. CHIN

Telephone No. (703) 308-0771

Shelia H. Vining
Paralegal Specialist
Group 2400